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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/124,280 07/29/98 PORRO

M 576008

EXAMINER

HM22/0412

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RYAN, V

ART UNIT

PAPER NUMBER

1641

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DATE MAILED:

04/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/124280

Applicant(s)

PORRO

Examiner

V. RYAN

Group Art Unit

1641

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/10/2000
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-54 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-54 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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DETAILED ACTION

The Examiner acknowledges receipt of the amendment filed January 10, 2000.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In this application:

Claim 54 was added.

Claims 1, 2, 9, 30, 34 and 35 were amended.

Claims 1-54 are now pending and under examination.

Response to Amendment

The declaration of Massimo Porro under 37 CFR 1.132 filed January 10, 2000 is sufficient to overcome the rejection of claims 1-51 and 53 based upon the reference of Velucchi et al under 35 U.S.C. 103.

(1) The objection to the drawings is maintained for reasons of record.

(2) The objection to the disclosure is withdrawn.

(3) The rejection of claims 1-10, 12-16 and 51-53 under 35 U.S.C. 112, second paragraph is withdrawn. The rejection of claims 11 and 17-50 is maintained.

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Applicant has amended claims 1 and 2 to recite "comprising" instead of "of the formula." However, claims 3-52 also contain the same limitation, rendering these claims indefinite.

Claims 11 and 17-50 remain indefinite. While these claims refer to specific amino acid sequences, the sequences do not conform to the limitation set forth in the parent claim. For example, claim 1 recites that a peptide comprising the formula $(A)_n$ must contain either lysine or arginine and n represents an integer with a minimum value of 7. However, several claims, such as claim 18 do not meet this limitation. The $(A)_n$ in claim 18, $(Lys)_5$ has an "n" of only 5.

(4) The rejection of claims 1-34 and 51 under 35 U.S.C. 102(b) as being anticipated by Porro is maintained.

Applicant asserts that Porro does not teach combining the LPS with a "stoichiometric excess" of peptide.

Porro teaches what appears to be the same peptides as recited in the claims. Therefore, the term "stoichiometric excess" of peptides is viewed as a product-by-process limitation, absent evidence to the contrary.

(5) The rejection of claims 1-51 and 53 under 35 U.S.C. 103 as being obvious by Hancock et al or Velucchi et al in view of Porro is withdrawn.

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(6) The rejection of claim 52 under 35 U.S.C. 103 as being obvious by Porro (WO 95/03327) or Hancock et al in view of the Immunization Practices Advisory Committee is withdrawn.

The following are new grounds of rejections:

Double Patenting

Claims 1-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,358,933 and claims 1-11 of US Patent No. 5,371,186. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are all directed to peptides with specified formulas. Although the issued patents refer to the peptides as monomeric, linear polymeric, cyclic monomeric or cyclic polymeric peptides, the amino acid sequences and formulas appear to be the same.

Claim Rejections - 35 USC § 112

Claims 1-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the peptide, does not reasonably provide enablement for the use of the peptides as a vaccine preparation. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Septic shock (Sepsis) frequently leads to death and the art of treating or preventing the symptoms of toxemia is unpredictable. Dr. Roger C. Bone (JAMA 276(7):565-66, 1996 (August 21)) teaches that "all trials of new therapies for sepsis conducted to date have failed to show efficacy." (See especially page 565, second paragraph)

In addition, Cross et al (Infection and Immunity 61(7):2741-7, 1993) teaches that "the dynamic nature of the pathophysiologic events and the complex array of mediators generated in the septic process preclude accurate prediction of the efficacy of novel therapeutic agents from in vitro studies alone." (See especially page 2741, first paragraph).

Therefore, in view of the unpredictable nature of the art and the lack of working examples for preventing septic shock, it would require undue experimentation for one skilled in the art to practice the entire scope of the claimed invention.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. US Patent #5,371,186
2. US Patent #5,358,933
3. US Patent #5,589,459

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

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Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
March 2000
Ryan/vr


JAMES C. HOUSEL 3/27/00
SUPERVISORY PATENT EXAMINER